UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

DEFENDANTS' OPPOSITION TO PLAINTIFFS' CROSS-MOTION FOR A PROTECTIVE ORDER

The ZHP Defendants moved to compel third party Valisure LLC ("Valisure") to comply with a narrow, targeted, non-burdensome subpoena regarding Valisure's testing of valsartan. Plaintiffs' opposition and cross-motion for protective order argues that the subpoena should be quashed because it: (1) is untimely; (2) does not seek relevant evidence; and (3) would burden plaintiffs and Valisure. Because plaintiffs' arguments lack merit, their cross-motion should be denied, and the ZHP Defendants' motion should be granted.

I. THE SUBPOENA WAS TIMELY.

As an initial matter, the subpoena at issue was timely. Plaintiffs assert that D.E. 863 closed all fact discovery in this litigation on August 2, 2021 (Pls.' Resp. at 1),[1] but that order merely set a deadline for defendants' expert reports regarding general causation and specifically contemplated that additional fact discovery ***and expert-related discovery*** would occur after that date. The other discovery deadline to which plaintiffs point is the deadline for "***Plaintiffs*** . . . to issue all subpoenas," but that does not mention third-party discovery by defendants. (*Id*. at 6 (emphasis added); *see also* ECF No. 575 ¶ 3 ("In advance of the September 30, 2020 conference, ***plaintiffs*** shall identify the entities they intend to serve with third-party

[1] Plaintiffs actually reference D.E. 864, but since that is a waiver of service, the ZHP Defendants assume it was a typographical error.

document subpoenas. The subpoenas shall be served by October 15, 2020.") (emphasis added).)

Even if the Court had intended to set a deadline for all third-party subpoenas, or the end of all fact discovery, good cause exists to allow the limited discovery sought by the ZHP Defendants. As explained in the ZHP Defendants' opening memorandum, the discovery sought from Valisure is highly relevant to ongoing expert discovery, and its relevance only became clear recently. *See* Fed. R. Civ. P. 16(b)(4) (permitting a judge to modify a schedule "for good cause"); *Boyington v. Percheron Field Servs., LLC*, No. 3:14-cv-90, 2017 WL 5633171, at *2 (W.D. Pa. Nov. 21, 2017) ("A court may find good cause to amend the scheduling order where the movant learns of the facts supporting [the motion] after expiration of the relevant filing deadline[.]") (citation omitted).

Although Valisure submitted its Citizen Petition in 2019, it was not clear at the time that the identity of the Novartis products referenced therein would be a contested issue in this case until: (1) plaintiffs' expert Dr. Ron Najafi disclosed his role in validating the testing results underlying the Citizen Petition during his 2022 deposition (Dep. of Ron Najafi ("R. Najafi 2022 Dep.") 145:13-15, Feb. 3, 2022, ECF No. 2033-4 ("***Q:*** And you had validated the test results that are reported in [Valisure's 2019 Citizen Petition]? ***A:*** Yes.")); (2) plaintiffs' counsel suggested in subsequent briefing that the Novartis product tested by Valisure was not Diovan or

Exforge, but a generic valsartan product (*see* Pls.' Br. in Opp'n to Defs.' Mot. to Compel Produc. of Testing & Other Materials in Possession of Class Expert, Dr. Ron Najafi at 4, ECF No. 2023); and (3) a number of plaintiffs' experts disclosed opinions on October 31, 2022 based on the assumption that neither Diovan nor Exforge contains any nitrosamines. Given these recent developments, the ZHP Defendants should be permitted to confirm that Valisure ***did*** test Diovan and/or Exforge and identified NDMA in these brand-name drugs in connection with challenging plaintiffs' experts' opinions.

II. THE NDC IDENTIFICATION NUMBERS FOR THE NOVARTIS SAMPLES TESTED BY VALISURE ARE CLEARLY RELEVANT TO TESTING PLAINTIFFS' EXPERTS' OPINIONS.

As noted above, the identifying NDC numbers for the Novartis valsartan samples tested by Valisure are directly relevant to plaintiffs' experts' opinions that Novartis's valsartan was adulterated because it contained NDMA, whereas name-brand Diovan/Exforge do not. Plaintiffs' arguments to the contrary are baseless.

First, plaintiffs contend that Valisure's Citizen Petition is irrelevant because defendants have not questioned certain plaintiffs' experts about this issue in their depositions. (Pls.' Resp. at 10-11.) That is incorrect. Defendants questioned Dr. Najafi at length about the Citizen Petition, and Valisure's finding of NDMA in a Novartis product, at his recent deposition. (*See* Dep. of Ron Najafi 144:2-162:22, Jan. 18, 2023.) In addition, defendants recently asked a number of plaintiffs'

experts at their depositions for the MSP matter whether they are aware that NDMA was found in the Reference Listed Drug and whether their opinions would change if that were the case. (*See, e.g.*, Dep. of Philip James Russ 148:3-25, Jan. 5, 2023 (rough); Dep. of Kali Panagos 160:5-8, Jan. 11, 2023 (rough); Dep. of Laura M. Plunkett 123:12-15, Jan. 12, 2023.)[2] This questioning reflects the centrality of the Diovan issue to plaintiffs' experts' theories.

Second, plaintiffs argue that any information related to Valisure's testing is irrelevant because the FDA criticized Valisure's testing method, citing an untitled letter issued by the FDA to Valisure in December 2022. (Pls.' Resp. at 13-15.) But the FDA letter related to an inspection of Valisure in Summer 2021, long after the Citizen Petition was submitted, and it referenced testing related to ***other*** products and potential impurities. (*See* Ex. G to Pls.' Resp.) Moreover, any criticism that plaintiffs (or the FDA) may have of Valisure does not undermine the relevance of the very limited, specific information the ZHP Defendants seek. Plaintiffs are free to argue at trial that Valisure's testing in connection with the 2019 Citizen Petition was unreliable, even though their own expert's laboratory

[2] Pursuant to the Confidentiality and Protective Order entered in this case, a deposition transcript is to be treated as confidential for 30 days following the issuance of the transcript. (ECF No. 139 at 12.) The ZHP Defendants will provide the relevant pages of the recent deposition transcripts that are cited under seal at the Court's request.

expressly validated some of the Valisure results. (*See* R. Najafi 2022 Dep. 144:8-145:15; Expert Decl. of Ron Najafi, Ph.D. (Apr. 25, 2022), ECF No. 2023-3.) But that does not make information confirming that Valisure tested and found NDMA in Diovan and Exforge any less relevant for purposes of discovery. *See, e.g.*, *Kreps v. Dependable Sanitation, Inc.*, No. 4:21-CV-04108-KES, 2022 WL 4094124, at *4, *6 (D.S.D. Sept. 7, 2022) (granting motion to compel testing that could "alter the balance of the evidence at trial" and noting that whether testing was unreliable "was an issue of evidence for consideration at trial, not grounds for objecting to relevant discovery").

In short, the limited evidence sought is highly relevant and should be produced.

III. Plaintiffs Have Not Identified Any Legitimate Burden Associated With The Subpoena.

Finally, plaintiffs cannot refute that Valisure will not face any real burden if it is directed to comply with the subpoena, which merely requires it to identify listed NDC numbers for the samples it tested. In a single sentence in their 16-page brief, plaintiffs generally assert that allowing the ZHP Defendants to obtain the NDC numbers for the Novartis samples Valisure tested "would be unduly burdensome and prejudicial to Plaintiffs (and Valisure)" because it would "re-open discovery" in this case. (Pls.' Resp. at 12-13.) That statement is baseless. Producing NDC numbers would merely require Valisure to send a letter providing

basic information from its testing files. That would not be burdensome to Valisure; nor would it subject Valisure to any additional discovery.

Further, plaintiffs' argument that such limited discovery would "upend[] the entire litigation" (Pls.' Resp. at 12) merely confirms the relevance of the Diovan question and why the benefits of the discovery would far outweigh the non-existent burden of disclosing NDC numbers. Defendants have previously taken the position that Valisure's Citizen Petition demonstrates that NDMA has been identified in Diovan/Exforge. Indeed, this was the subject of significant briefing leading the Court to compel Dr. Najafi to produce information related to his laboratory's validation of some of the testing underlying the Citizen Petition. (*See* Special Master Order No. 68 at 6, ECF No. 2137.) As a result, allowing the ZHP Defendants to obtain NDC numbers for the Novartis samples in which Valisure found NDMA would not inject new arguments or issues into the litigation. It would simply confirm what defendants have argued is clear from the Citizen Petition itself.

CONCLUSION

For these reasons, and those set forth in the ZHP Defendants' opening brief, the ZHP Defendants respectfully request that the Court enter an order compelling Valisure to comply with the ZHP Defendants' December 14, 2022 subpoena by identifying the NDC numbers for the Novartis valsartan products that Valisure

tested in connection with its Citizen Petition to the FDA, and deny plaintiffs' cross-motion for a protective order.

Dated: January 23, 2023

Respectfully submitted,

By: */s/ Jessica Davidson Miller*
Jessica Davidson Miller (DC Bar No. 457021)
Liaison Counsel for Manufacturer Defendants
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
Telephone: (202) 371-7000
Facsimile: (202) 661-0525
jessica.miller@skadden.com

Allison M. Brown
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
Phone: (212) 735-3222
Fax: (917) 777-3222
Allison.Brown@skadden.com

Attorneys for Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare U.S., LLC

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 23, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson Miller
Jessica Davidson Miller (DC Bar No. 457021)